

WHAT IS CLAIMED IS:

- 5/2/07
1. A balloon catheter, comprising
 - a) an elongated shaft having a proximal end, a distal end, and at least one lumen therein; and
 - b) a radially noncompliant balloon formed at least in part of a polycarbonate polyurethane block copolymer having a compliance of less than about 0.025 mm/atm in the working pressure range of the balloon, the polycarbonate polyurethane block copolymer comprising the product of the reaction of poly(1,6-hexyl 1,2-ethylcarbonate) diol and 4,4'-methylene bisphenyl diisocyanate (MDI) and a chain extender.
 2. The balloon catheter of claim 1 wherein the balloon compliance is about 0.012 to about 0.016 mm/atm in an inflation pressure range of about 7 to about 22 atm.
 3. The balloon catheter of claim 1 wherein the polycarbonate polyurethane block copolymer has a tensile elongation at break of at least 250%.
 4. The balloon catheter of claim 1 wherein the polycarbonate polyurethane block copolymer has a tensile elongation at break of about 255% to about 320%.
 5. The balloon catheter of claim 1 wherein the balloon is axially noncompliant.

6. The balloon catheter of claim 1 wherein the chain extender comprises 1,4-butanediol.

7. The balloon catheter of claim 1 wherein the polyurethane block copolymer has a flexural modulus of at least about 300,000 psi.

8. The balloon catheter of claim 1 wherein the balloon comprises an expanded extruded polymeric tube comprising the polyurethane block copolymer.

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9. The balloon catheter of claim 1 wherein the balloon rupture pressure is greater than about 18 atm.

10. A method of making a radially and axially noncompliant balloon for a catheter, comprising

a) extruding a tubular product formed at least in part of a block copolymer, having a first outer diameter and a first inner diameter;

b) annealing the tubular product at not less than about 50°C.

c) heating the tubular product at a first elevated temperature, and radially expanding the tubular product to a second outer diameter;

d) heating the expanded tubular product at a second elevated temperature not less than the first elevated temperature; and

e) cooling the expanded tubular product to form the noncompliant balloon.

11. The method of claim 10 wherein the extruded tubular product is annealed for about 16 to about 24 hours.

12. The method of claim 10 wherein the extruded tubular product is annealed at about 55°C.

13. The method of claim 12 wherein the extruded tubular product is annealed for about 16 hours.